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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,613	08/17/2001	James P. Beltzer	DYXHGS-025.1 US	5083

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/08/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,613	BELTZER ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-71 are pending.

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:1***, classified in Class 514, subclass 9.

II. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:2***, classified in Class 514, subclass 9.

III. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:3***, classified in Class 514, subclass 9.

IV. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:4***, classified in Class 514, subclass 9.

V. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:5***, classified in Class 514, subclass 9.

VI. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:6***, classified in Class 514, subclass 9.

VII. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:7***, classified in Class 514, subclass 9.

VIII. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:8***, classified in Class 514, subclass 9.

IX. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:9***, classified in Class 514, subclass 9.

X. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:10***, classified in Class 514, subclass 9.

XI. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:11***, classified in Class 514, subclass 9.

XII. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:12***, classified in Class 514, subclass 9.

XIII. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:446***, classified in Class 514, subclass 18.

XIV. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:447***, classified in Class 514, subclass 14.

XV. Claims 1-69 and possibly 70 and/or 71, drawn to methods of treating, preventing or ameliorating a disease or disorder associated with aberrant BLyS or BLyS receptor expression or activity by administering or contacting with *a BLyS binding polypeptide comprising the amino acid sequence set forth in* ***SEQ ID NO:448***, classified in Class 514, subclass 15.

Claim 69 links inventions I-XIV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 69. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The Inventions are distinct, each from the other because:

4. Groups I-XV are different methods. Each method differs with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed inventions:

A) *Irrespective of which Group is elected* Applicant is required to elect a specific peptide in which the amino acid sequence of **each position is defined by a single amino acid**, and provide the corresponding SEQ ID NO:.

These species are distinct because each peptide possess a unique structure. Currently, claim 69 is generic.

B) *Irrespective of which Group is elected*, Applicant is required to elect a method with respect to a specific disease or disorder from among those recited (e.g. in claims 5-8 or in the specification on pages 15-16) that is appropriate for the species of peptide; i.e., Applicant is *further required* to identify whether the effect of the elected peptide on the disease or disorder or aspect of B cell function recited is inhibitory or stimulatory.

An election of subgenus such as "an autoimmune disease" which does not set forth a specific disease (e.g., rheumatoid arthritis) will be held non-responsive.

These species are distinct because each of the numerous diseases differ with respect to their etiologies, the patient populations involved, and their therapeutic endpoints; thus each specific method represents patentably distinct subject matter. Currently, claim 69 is generic.

Applicant is required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
April 7, 2003

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PRIMARY EXAMINER
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4/7/03